K090980

Pg 1 of 3

JUN 29 2009

510(k) SUMMARY

HD EndoEYE - High Definition Digital Video Laparoscope

1. General Information

Applicant:	Olympus Winter & Ibe GmbH Kuehnstrasse 61 * 22045 Hamburg * Germany Establishment Registration No: 9610773
Official Correspondent:	Stacy Abbatiello Kluesner M.S., RAC Regulatory Affairs & Quality Assurance Olympus America Inc. 3500 Corporate Parkway, PO Box 610 Center Valley PA 18034-0610 Phone: (484) 896-5405 Facsimile: (484) 896-7128 Email:Stacy.Kluesner@olympus.com Establishment Registration No: 2429304
Manufacturer:	Olympus Winter & Ibe GmbH Kuehnstrasse 61 * 22045 Hamburg * Germany Establishment Registration No: 9610773

2. Device Identification

Device Name:	WA50011A/WA50013A/WA50013L/WA50013T/WA50015L HD EndoEYE - High Definition Digital Video Laparoscope
Common Name:	HD EndoEYE
Class:	II
Regulation Number / Name:	21 CFR 876.1500 Endoscope and Accessories 21 CFR 874.4720 Mediastinoscope and Accessories 21 CFR 884.1720 Gynecologic Laparoscope and Accessories
Product Code:	GCJ, NLM, KOG, NWB EWY NMH/HET
Classification Panel:	Gastroenterology/ Urology Ear Nose & Throat Obstetrics/Gynecology

3. Legally Marketed Device to which Substantial Equivalence is claimed

The following table shows the subject and predicate device to which we claim substantial equivalence.

Table 11.1 Subject & Predicate Devices

Subject Device (Part of this submission)	Predicate Device	PD's 510(k)No.
HD EndoEYE WA50011A, WA50013A, WA50013L, WA50013T, WA50015L	A4941A, A4943A OES Laparo-Thoraco Videoscope	K955456
	HD EndoEYE Laparo-Thoraco Videoscope OLYMPUS LTF-VH	K080948

4. Device Description

The HD EndoEYE - High Definition Digital Video Laparoscope is a video endoscope used for endoscopy and endoscopic surgery within the abdominal cavities which is basically identical to the predicate device, OES Laparo- Thoraco Videoscope, for the same application areas.
The major difference from the predicate device is only the NBI function added to the subject device.

When the CLV-180 and CV-180 or the OTV-S7Pro and CLV-S40Pro are combined with HD EndoEYE, both an endoscopic image by white light illumination and that by NBI illumination can be observed within the thoracic and abdominal cavities. The CV-180 identifies when an NBI-compatible scope is connected, by using the Scope ID function provided with the scopes.

5. Indications for Use

HD EndoEYE High Definition Digital Video Laparoscope:
This instrument has been designed to be used with a video system center, light source, documentation equipment, monitor, hand instruments, electrosurgical unit, and other ancillary equipment for endoscopy and endoscopic surgery within the thoracic and abdominal cavities.

6. Comparison of Technological Characteristics

The HD EndoEYE is mainly similar to the predicate devices in specifications without NBI function. Comparison between the subject and predicate devices is shown below.

Table 11.2 Comparison of Specifications

Specifications	Subject Device HD Endo EYE	Predicate Device OES	Predicate Device LTF-VH
Field of View	80°	70°	90°
Depth of field	20 to 120 mm	18 to 100 mm	15-100mm
Direction of View	0°, 30°, 45°	0°, 30°	0°
Outer Diameter of Distal End	10	11	10mm
Optical System	Color	Color	Color
Working Length	250-390mm	320mm	370mm
Switch for NBI function	Provided	Not provided	Provided

7. Conclusion

When compared to the predicate devices, the HD EndoEYE does not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2009

Olympus Winter & Ibe GmbH
% Stacy Abbatiello Kluesner, RAC
Regulatory Affairs & Quality Assurance
Olympus America, Inc.
3500 Corporate Parkway
P.O. Box 610
CENTER VALLEY PA 18034-0610

Re: K090980
Trade/Device Name: HD EndoEYE
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: NWB
Dated: April 3, 2009
Received: April 14, 2009

Dear Ms. Kluesner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

OLYMPUS

Indications for Use

510(k) Number (if known): K090980
Device Name: HD EndoEYE

This instrument has been designed to be used with a video system center, light source, documentation equipment, monitor, hand instruments, electrosurgical unit and other ancillary equipment for endoscopic diagnosis and treatment within the abdomen and thoracic cavities including the female reproductive organs.

Prescription Use ✓ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K090980